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Units 13 – 16

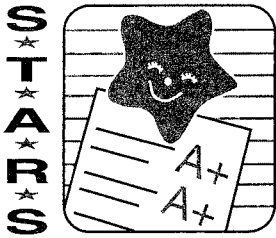
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Prepared by: Carolyn J. Frigmanski, M.A., B.S.R.T. ®
Founder, S.T.A.R.S.



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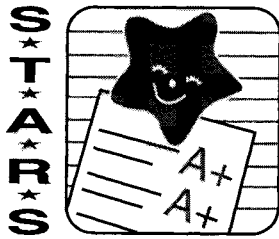
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A handwritten signature in cursive script, appearing to read 'Carolyn', is written over a horizontal line.

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UNIT NUMBER 13

VIRTUAL REALITY IN MEDICAL APPLICATIONS

PREPARED BY: Carolyn J. Frigmanski, M.A., B.S.R.T. (R)

INTRODUCTION

In this unit we will introduce some of the key concepts and current applications of virtual reality in the medical field. I hope all of you will take the opportunity to play with virtual reality computer games as simulation so that you may experience the excitement of a new imaging modality up close.

DEFINITIONS

In 1989, Jaron Lanier coined term virtual reality. There are many definitions used interchangeably throughout the world. Some of these definitions include:

- an advanced human-computer interface that simulates a realistic environment and allows participants to interact with it;
- virtual environments are three dimensional, computer-generated worlds, which accurately model and simulate an actual environment, whether it is a physical structure or an aggregation of different types of data;
- a graphic representation of data constructed from the banks of every computer in the human structure;
- computer generated representation of an environment that allows sensory interaction, thus giving the impression of actually being present through sight, sound and touch.

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In addition to the many definitions relative to virtual reality, there are multiple synonyms. Some of these synonyms include:

Artificial reality
Virtual environments
Cyberspace
Visually coupled systems
Telepresence
Virtual presence

EVOLUTION OF VIRTUAL REALITY

Virtual reality has its historical physics foundation in stereoscopy. Stereoscopy deals with 2-dimensional drawings or photographs that, when viewed by both eyes, appear to exist in three dimensions. You may recall having a View Master when you were a child or have used your child's toy. Small circular discs with pictures were inserted into the View Master. As you clicked the lever, a new image would rotate and you would view it through the lens. The images appeared 3-dimensional. The members of the pair of pictures show the same scene or object from slightly different angles that correspond to the angle of vision of the two eyes of the viewer. The left eye view and the right eye view of the object are perceived from different angles. The brain combines and interprets the information in terms of depth based on the different distances to the points and objects seen. You may also have had grandparents who used a stereoscope with postcards having two images on them.

To produce 3-dimensional movies, the left- and right-eye images must be projected simultaneously but distinguished by different colors or polarization. You may have used binocular viewing filters while seated in the audience.

Virtual reality witnessed its birth in the 1950s when the military created flight simulators for training purposes of pilots and strategic flight planning over various terrains. Virtual reality applications became more prevalent in the 1960s as computer graphics became more available. In 1965, Sutherland developed the first computer-based, head-mounted display used for aerospace pilot training. In 1985 the availability of low cost liquid crystal devices (LCD) and the development of the VPL data glove created new opportunities for medicine using the present technology. The VPL data glove is a device that allows interaction with the computer-generated images.

KEY CONCEPTS

Immersion is the degree to which a subject feels that he is actually present in a virtual environment. Interactivity relates to the role of the user changing from observer to participant in a virtual environment. Awareness of the movements in relative positions of various parts of the body in the virtual environment is referred to as haptic or kinaesthetic feedback. This feedback is gained by the sense of touch or pressure of various objects within the environment.

NEUROSURGERY

In the April 1996 issue of Neurosurgery, Michael L. J. Apuzzo, M.D. was quoted as saying, "We are entering an exciting era of advanced surgery of the human cerebrum." Structurally based surgical maps for preoperative planning and intraoperative tactical direction have become available. Virtual reality-based stations are being used for operative rehearsal simulation, training, and ultimately actual surgery. There is enhancement of operative events through robotic interfaces. Ultimate surgery departments and robotic systems for precise surgery are being designed. There are new dimensions of ablation through the use of radiant energy and capabilities of functional restoration, such as a miniature linear accelerator in a 13 gauge cannula with the ability to use electrons and formulate x-rays at the tip (undergoing testing at ten different institutions throughout the world). Photodynamic therapy is the IV administration of photoreactive dyes which establish a capture net in neoplasms. Monochromatic red light effects a coagulation necrosis and boron capture therapy is under investigation.

VIRTUAL ENDOSCOPY

In Radiology, July, 1996, it was noted that more than a dozen commercial companies and academic institutions are actively pursuing this technology. Colo-rectal cancer is an important public health concern since it is the second leading cause of cancer-related deaths in the United States today and can be prevented if precursor polyps are discovered and removed early.

VIRTUAL BRONCHOSCOPY

Chest, February, 1996 published the use of data sets derived from helical CT. A virtual reality simulation accurately represented major endobronchial anatomic findings, i.e. has a role in prebronchoscopy planning, training and therapy. Simulated airway walls can be rendered semitransparent, thereby revealing extrabronchial structures for tissue sampling.

OTORHINOLARYNGOLOGY

The British Medical Journal, November, 1994, stated that a viewing wand as an intraoperative image guidance system with a proprioceptive robot-like arm attached to a standard 3 pin Mayfield headrest has been used since 1992. Using preoperative CT or MR imaging scans, the wand creates almost instantaneous 3-D or triplanar (sagittal, coronal and axial) computerized reconstructions that proved extremely useful in identifying the relation and proximity of important anatomical structures and resection of lesions in the ear, nose and throat.

Using a special bayonet probe, it can be used for the pituitary fossa and sinus surgery.

ANESTHESIA

British Journal of Anesthesia, 1995 published the following possible virtual reality applications in the future.

-simulate actual event at no risk to patient,

- simulate actual events repetitively,
- ability to halt simulation for discussion,
- allows uncommon events to be experienced,
- allows errors to be made and consequences explored,
- provides an objective record of performance,
- allows control of independent or multiple variables in a system or situation

CAE Virtual Anesthetic Simulator has actual monitors and anesthetic machines connected to a computer console which controls the responses of a manikin named JACK (fully articulated computer-aided design model of a human being) to a choice of 40 simulated events

LAPAROSCOPIC SURGERY

Preliminary experiments by Philip Green, Director of Biomedical Engineering Research Laboratory at Stanford Research Institute includes a prototype with the dexterity of a remotely connected scalpel that can slice a grape into 1 mm thicknesses. It is presently used to conduct cholecystectomy and small bowel anastomosis ex vivo on porcine viscera. The arm is controlled by the surgeon's head movements. An activating foot pedal safeguards against disaster if the surgeon sneezes.

The British Journal of Surgery, 1994 stated a surgical simulator is being developed in conjunction with VPL Research (Redwood City, California) which is realistic in its anatomical and technical accuracy. The first practical application of virtual reality laparoscopic surgery was in Virtual Clinic (Cine-Med, Woodbury, CT). In cholecystectomy, 3-D liver, gallbladder and related structures with texture incorporates four real instruments: fan retractor, scissors, grasping forceps, and clip applicator.

Future plans for the Virtual Clinic include creation of additional anatomical landscapes such as abdomen, thorax, pelvis and heart, software to interpret CT and MR scans to assist in 3-D representation of diseased anatomy, practice surgery before actual surgery application of robotics that envision surgeons to be able to perform procedures while operating from a distant site (telepresence). The operator and assistants prepare the patient and place laparoscopic instruments linked to a robotic system in the abdomen. The surgeon goes to a workstation to observe 3-D views of the operation and controls instruments with special interfaces that allow full sensory feedback.

INTERVENTIONAL RADIOLOGY

ADVANCE for Radiologic Science Professionals, March, 1996 states there would be actual virtual reality demonstrations at the Society of Cardiovascular and Interventional Radiology meeting in March, 1996. Residents at Massachusetts General Hospital in Boston use virtual reality to learn stent placement, thrombolysis, breast biopsy and contrast injection. There is much interest in using virtual reality to test new devices. High Techsplanations Technology has a unit that does not require a head mounted display and costs \$35,000. A Paris-based research group is developing an ultrasound simulation system for sonographers and physicians. Abbott Laboratories is developing contrast media that would allow certain tissues like muscle to virtually disappear. CT angiography applications exist now.

OTHER APPLICATIONS

British Medical Journal, January, 1994 states that new materials will allow changes in surgical instrument construction such as the use of "memory metals" to make heat activated scissors or forceps. Present optical endoscopic systems are undergoing refinements and modifications to digital systems with even smaller electronic chip cameras. Binocular and autofocus zoom systems will provide 3-D manipulation to a high definition television monitor for others to see and assist in procedures. Simple robotics combined with x-ray or ultrasonal imaging include automatic transurethral resection of the prostate gland and one for measuring and removing the femoral medullary cavity before insertion of a hip prosthesis. The OR of the future will have specially equipped treatment rooms with combined a-v, ultrasound scanning and x-ray facilities that are permanent installations with dedicated trained staff to manage them.

The Lancet, May, 1994 stated that virtual reality can be used to explore phobias. Use the data glove as a medium for translating sign language into synthesized speech.

"ADAM" (Animated Dissection of Anatomy for Medicine) is an extensive collection of 2-D anatomical drawings in which the user can strip away the tissues layer by layer and cut sections to give a 3-D effect.

Science, August, 1994 published the findings of tests conducted at the University of North Carolina Nanomanipulator. By displaying the molecular model, Cody can immerse herself in the structure and use a mechanical tracking arm to explore it by touch and can feel the interactions of one molecule docking inside another by computer calculations of overall repulsion/attraction of electromagnetic forces among the atoms. Future manipulation of DNA, proteins, enzymes and other biomolecules could be studied to a greater degree.

NURSING IMPLICATIONS

Nursing Science Quarterly, Spring, 1993 stated virtual reality will be used to simulate nursing stations and care plans, especially in critical care and emergency room, for practice sessions before actual use. Nurses become virtual reality patients to enhance empathy of real patients. Patients can experience procedures before they are subjected to them. It will also provide the ability to build and control traffic patterns. Applicants considering admission to nursing programs of study can "feel" what it is like to be a nurse.

REALIGNMENT OF SPECIALISTS

The practice of medicine as it exists today may change in the next millennium. It is anticipated that there will be a realignment of specialists and some newly created individuals will be necessary to operate in a virtual world effectively and to support the needs of good patient care.

The specialists will include:

- physician director — assigns patient to care of appropriate member of the interventional team;
- anesthetist — responsible for pre and postoperative care;
- endoscopist — performs endoscopic exams on gall bladder, kidney, uterus, hernia or appendix;
- interventional radiologist — treat organs amenable to his/her techniques;

- bioengineer — consulted about suitable instrumentation;
- health economist — decide whether a recommended procedure is financially and politically acceptable.

PRACTICAL CONSIDERATIONS

The availability of virtual reality at this time in history is somewhat limited. Some of the considerations, which must be overcome, include:

- the availability of virtual reality to the population at large;
- training of individuals to administer these methods;
- definition of acceptable level of expertise;
- containment of costs, allocation of research dollars (University of Southern California = \$2 million for one operating room);
- supportive popular attitudes and demands, and
- concurrent progress in transferable technical and biological areas.

CONCLUSION

Some of the problems in the proliferation of virtual environments involve the time constraints of our existing computer systems. As our technology improves and the transaction time becomes fractional, virtual reality will become more prevalent and more cost effective. The present head-mounted displays are much too cumbersome. Hopefully, as our electronic engineering changes, these head-mounted displays will become smaller and more flexible in allowing a greater degree of head movement and correlation to the manual dexterity. The data gloves that have been established are large and somewhat cumbersome too. Hopefully, a tactile feedback system will be created to minimize the size and capability for manual dexterity in manipulating small anatomic structures within the human body.

The science fiction world that was and is promoted today will definitely change as our electronic and computer generations improve. There is no question that there is a great deal of optimism for the application of virtual reality in surgical interventions in the 21st century. The younger generation of radiographers should be advised to strengthen their knowledge base and applications in computer skills since there is no question that picture archiving and communication systems will be more prevalent and easily interfaced to the applications of virtual reality.

This concludes unit 13. Please proceed to the unit questions and complete the required personal data.

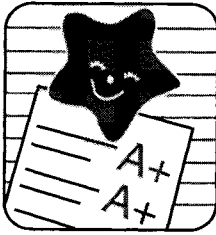
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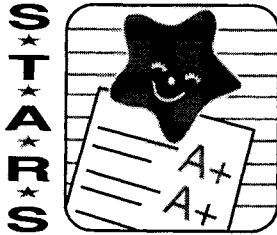
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Unit Number 14

PICA: A Look at PICA Versus Foreign Bodies

Prepared by: Carolyn J. Frigmanski, M.A., B.S.R.T. (R)
And Tammi Brown

DEFINITION OF PICA

PICA is the Latin word for magpie, a scavenger bird. It is defined as the eating of non-edible food items, i.e.

plaster	dirt	matches	feces
putty	crayons	string	paint
wood	cloth	paper	
cigarette ashes		laundry starch	

FACTORS AFFECTING PICA

There are many factors which influence the development of PICA. Each factor will be described.

Cultural:

Geophagia (clay eating) has been known to occur on every continent. In certain cultural groups in Africa, it is believed that soil may have magical properties that lead to well being. A number of African groups actually mine specific clay deposits as food. It is considered a delicacy, a sort of "sweet". This practice of clay eating still exists in the southern United States as a result of the slave trade. PICA was so common among black slaves that sometimes mouth locks were used to prevent suicide by ingestion of excessive quantities. Some Indian groups in the Amazon eat blocks of clay with their meat.

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Socioeconomic:

A survey of the prevalence of PICA in three groups of children age 1-6 revealed:

<u>Income Group</u>	<u>% PICA Occurrence</u>
Low Income	32%
Middle Income	5%
High Income	5%

This survey statistically shows a significant difference between the percentage of PICA in low-income families versus those children in middle and high-income families due to the unavailability of food and to the lack of available mothering.

Emotional Deprivation

The type and amount of available parental control particularly with children who have high levels of mouth activity are crucial in the development of PICA as a symptom.

Some mothers encourage the child's use of oral satisfaction as a means of coping with anxiety. Psychic trauma due to separation from one or both parents occurs with significant frequency. Such separation may be in the form of physical separation such as the employment of the mother with replacement by inadequate or rapidly changing caretakers. Emotional difficulties in the mother, such as psychosis, depression, or alcohol and drug abuse, may render her unavailable for nurturing her child.

Constitutional Factors:

Exploration of the environment by mouthing is part of normal development. Its continuation past its normal phase limits (5-18 months) can lead to PICA.

Organic brain damage and mental retardation predispose some children to PICA. Parents of these children may be required to exert more external control as a means of helping the children forgo these activities.

FREQUENCY OF PICA

PICA is estimated to occur in 10 to 32% of children between the ages of one and six.

Among young children, there is no difference in prevalence between boys and girls.

In adults, however, the habit occurs more frequently in women than in men.

Certain forms of PICA, including geophagia (clay eating) and amylophagia (starch eating), have been reported to occur in pregnant women.

In a recent follow up study of 60 children who had PICA when young, twelve of the subjects (ages 12-25), still had PICA. Only two of the twelve were male.

In another study, 58% of children with PICA had siblings with PICA.

Mothers of children with PICA had a high incidence of PICA themselves (63%).

SYMPTOMS OF PICA

In Children:

Rocking
Nail biting
Hair pulling
Head banging
Thumb sucking

In Adolescents:

Fears
Enuresis
Stuttering
Nightmares
Constipation
Temper-tantrums
Uncontrolled aggression

In Adults

Poor ego
Nail biting
Clinical depression
Alcohol/drug abuse
Suicide attempts, thoughts, or gestures

Preliminary follow-up studies of children with PICA and retrospective studies of adults with addictions have led to the conclusion that *childhood PICA indicates an "addiction-prone" individual.*

CLINICAL IMPLICATIONS

PICA, often characterized only by the isolated symptom of eating non-nutritive substance, is easily missed unless the diagnosis is specifically sought. Therefore, PICA is perhaps most often recognized as a result of its various medical complications that may be serious.

Accumulation of hair, thread, and rags in the colon has occasionally resulted in:

intestinal obstruction
frequent constipation
nutritional anemia
gastric pain
diphtheria
lead poisoning (the symptom of PICA is still the primary etiologic factor in lead poisoning of young children)

tuberculosis
developmental retardation
rickets
death

CLINICAL CASE #1

"Doris", a female African-American, age 3, was hospitalized for lead poisoning caused by eating paint and plaster. The onset of her PICA was 10 months which started by ingesting lead pencils, fingers from her doll, newspaper, rocks, and sticks. "Doris' " mother was considered an immature single parent with three children who worked a full time job.

CLINICAL CASE #2

"Hannah", a female Caucasian, age 2, was the only child in her family. Her PICA, onset at 5 months, included eating wood, paint, dirt, coal, stones, and toys. She was found to be undernourished and had nutritional anemia. "Hannah's" father had a history of feeding problems and ate dirt in infancy. Her mother had attacks of nervous vomiting, similar to "Hannah", when she is displeased.

CLINICAL CASE #3

"Frank", age 3, was neglected, poorly and irregularly fed, and left alone in his crib most of the time. His primary caregiver was his grandmother who stated that she was "too ill and nervous" to care for him properly. "Frank" refused all nourishment other than milk. He would soil his clothes and eat his feces (coprophagy). His mother was psychotic and was finally committed to a psychiatric hospital after two suicide attempts. "Frank" was placed in a foster home and began to eat well within a few days. He ceased soiling and wetting himself, and the PICA ceased.

TREATMENT

World PICA clinics combine a medical and socio-psychiatric approach to the children and their families. The activities of the clinic are best performed by a multi-disciplinary staff consisting of:

Pediatrician
Nurse

Social Worker
Psychiatrist

A medical history includes:

- special attention to signs and symptoms of lead poisoning, including gastrointestinal or central nervous system symptoms
- evaluation of behavior, appetite, and PICA symptoms
- x-rays of the long bones and blood samples to check blood-lead level

An educational approach is used to teach parents the harmful effects of PICA. Mothers were encouraged to wean older children who were still taking the bottle and using pacifiers. More time doing parent-child activities are also encouraged.

Socioeconomic problems require an individual outline to meet the needs of child and mother. Social workers are able to help families with multiple problems utilize the usual community resources. Social agencies for immediate financial assistance or accommodations for better homes can be used. Visiting Nurses' Associations offer help toward better care of children. Mental Health clinics provide family counseling.

Children with more fixed and severe psychopathology consistently need psychotherapy before they could give up their PICA habits. Examples include:

- one child would dig holes in patched plaster;
- one child searched for laundry starch when candy was available;
- others cried for newspapers to chew on when food or Popsicles were offered.

PREVENTATIVE MEASURES

Primary prevention of PICA must be directed toward improving the mental health of children in infancy and early childhood. Social welfare programs are needed to prevent the disruption of family life by improving economic conditions so that mothering can be consistently available and adequate.

Conditions found in the environment, which expose a child with PICA to the development of lead poisoning such as lead-containing paint in housing, cribs, and toys, must be eliminated.

Measures designed to remove or to lessen factors known to predispose children to PICA may also have other long-term benefits. Among these is the elimination of some of the conditions contributing to emotional problems in later life, such as alcoholism and drug addiction.

COMPARISON WITH FOREIGN BODIES

A foreign body is an object or substance found in an organ or tissue in which it does not belong under normal circumstances such as a bolus of food in the trachea or particle of dust in the eye. It is difficult for the physician to ascertain accidental versus purposeful introduction of a foreign body without obtaining patient's history.

SADISM AND MASOCHISM

Sadism is defined as the obtaining of sexual gratification by inflicting pain.

Masochism is defined as the obtaining of pleasure, sexual gratification, by submitting to physical or mental cruelty.

Patients have come into the emergency department with foreign objects that were purposely introduced into a body orifice for sexual gratification.

CONCLUSION FOR PICA

PICA is composed of multiple etiologies with various factors contributing to different degrees in each child. Some of these factors are innate in the child's constitutional makeup and in his normal course of development and behavior. Some children are more prone to fall victim to PICA than others depending on their environment.

The prognosis for PICA is variable. In children, PICA usually resolves with increasing age; in pregnant women, PICA is usually limited to the term of the pregnancy. However, in some adults, especially in the mentally retarded, PICA may continue for years. Follow-up data on these populations are too limited to permit conclusion.

This concludes Unit 14. Please proceed to the unit questions and complete the required personal data.

Some Important Terms and/or Concepts in Unit 14

PICA defined as the eating of non-edible food items.

Geophagia (clay eating) has been known to occur on every continent.

PICA is estimated to occur in 10 to 32% of children between the ages of one and six.

Childhood PICA indicates an "addiction-prone" individual.

PICA is easily missed unless the diagnosis is specifically sought.

The symptom of PICA is still the primary etiologic factor in lead poisoning of young children.

An educational approach is used to teach parents the harmful effects of PICA.

Children with more fixed and severe psychopathology consistently need psychotherapy before they could give up their PICA habits.

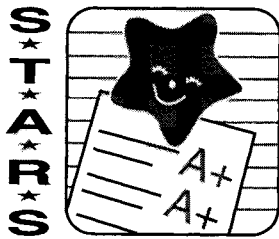
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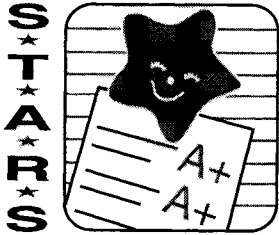
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UNIT NUMBER 15

The Evolutionary Process of Disease:

From Ancient Man to Modern Man

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MEDICAL ANTHROPOLOGY

Medical Anthropology is the study of disease in past and present day human populations which provides insight into the relationship between people and their environment. Changing disease patterns reflect the net effect of:

- | | | | |
|-----------------|-------------|-----------|------------------------|
| *demography | *vegetation | *culture | *economic exploitation |
| *climate | *nutrition | *behavior | *social structure |
| *dietary habits | *religion | *genetics | *migration |
| *occupation | | | |

Medical anthropology investigates the dimensions of time, culture, and biology with methods of comparative and wholistic analyses.

DEFINITION OF DISEASE

There are multiple definitions published. The definition we will use as our standard of reference is an "impairment of health and well-being". Health may be more appropriately viewed as an ongoing process in which an organism's functions such as biological, psychological and sociological are in equilibrium with the environment. Disease occurs when the organism is not functioning in equilibrium.

This unit is a part of a continuing education program for Radiographers and General X-Ray Machine Operators. This unit is not valid for continuing education credit without a certificate signed by an official from S.T.A.R.S.

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EPIDEMIOLOGY

Epidemiology means literally "science of epidemics". It is a discipline that has evolved relatively specialized methods for investigating health problems, not only epidemics, but also all other forms of disease and bodily injury i.e.

cancer
suicide

heart disease
alcoholism

automobile accidents
drug addiction

An epidemiologist is an individual concerned with exploring human ecology as it relates to the health of human beings and their environment. They study the origin and distribution of health problems in a population through the collection of data from many different sources.

PALEOPATHOLOGY

Paleopathology is the science of diseases that can be demonstrated in ancient man and animals. The objectives in studying paleopathology are:

- to analyze and describe the evolution of diseases that have affected man;
- to provide information about the cultural circumstances of a given population; and
- to provide understanding about the mechanisms of human adaptation to a changing environment.

Non-human reptilian evidence of disease has been estimated to have existed 250,000,000 years ago.

Paleopathology deals with prehistoric and non-literate societies by investigating skeletal materials and soft tissues as physical evidence of disease and/or physical injury.

THE HOST-AGENT INTERACTION

The host is an organism that provides a nutritional environment for another organism. The agent is the invading organism or cause of a disease. The long-term survival of an organism depends on its viability. Viability includes its ability to survive in a free state, growth requirements, and host range. The host range is the spectrum of animals and arthropods an agent can successfully parasitize or infect and its vulnerability to chemotherapeutic or antibiotic substances.

MODES OF TRANSMISSION

Agents can transmit disease in the following manner. Agents can escape from the source host- i.e. emergence of an agent from the infected source.

Conveyance to the recipient host may occur by

- a. direct contact/no vector - kissing, sexual intercourse, etc.
- b. indirect - involves a vector which can be inanimate i.e. infected water droplets or food or animate i.e. an animal that experiences the infection with multiplication of the microbial agent before transmission occurs i.e. lice, flies.

HOST-DEFENSE SYSTEMS

Contact with an agent may result in inadequate dosage or unsuitable portal of entry or specific host immunity. The parasite fails to lodge and establish an infection. The infection may be established, but remains subclinical. The infection may cause disease.

LINES OF DEFENSE

The human body has several lines of defense to prevent infective agents from causing disease. These lines of defense include:

1. intact skin and mucous membrane to resist penetration;
2. functional i.e. coughing to rid respiratory passage of harmful substance;
3. pain, touch, smell, taste, sight and hearing to activate an evasive action if danger threatens;
4. immunological response of antigens and the production of protective antibodies.

SEASONAL EFFECTS AND TRANSMISSION

Contact with vectors or organisms shows several patterns relative to the season and the level of transmission. For example, the tsetse fly cannot withstand high temperature. Scarcity of food such as drought may cause under-nourishment or folic acid deficiency in which the human being becomes particularly sensitive to infection. The mosquito for yellow fever transmission needs water to breed.

MAJOR CONCEPTS

The primary concepts relative to the transmission of disease have been established by anthropologists, medical sociologists and epidemiologists. When human beings lived as nomads or in widely scattered and isolated communities, the danger of epidemics and infectious disease was slight. Crowding in primitive cities with unsanitary living conditions and an abundance of rats and lice increased the risk of developing communicable diseases because diseases could spread more quickly and the disease-causing micro-organisms would persist within a community for longer periods of time. Contact with human wastes lead to endemic enteric bacterial infections.

Herding practices involved close contact of animals, healthy and unhealthy, and human beings that promoted transmission of infectious disease. Products of domesticated animals such as hair, milk and skin could transmit infection such as anthrax, TB and/or brucellosis.

Three new patterns of migration of peoples from one region of the world to another spread a disease for the first time. The earliest new disease transmission occurred in the 1st Christian centuries when caravans and ships linked China and India with the Mediterranean. This disease transmission may be partially responsible for the collapse of the Roman and Chinese Empires. The establishment of the Mongol Empire in northern Eurasia in the 13th century promoted bubonic plague via rats in the saddlebags of the caravans. The openings of the waterways for trade, the return of the Crusaders and recent crop failures prompted people to move into already

crowded cities. Bubonic plague apparently reached Europe from China during the 14th century. Cholera entered Great Britain by way of India in the 17th century. Europeans brought smallpox to the Western Hemisphere during the exploration and settlement of the New World.

European colonization was responsible for the following events:

- 1749 - severe epidemics of measles in the Amazon
- 1829 - severe epidemic of measles in Estonia
- 1846 - severe epidemic of measles in the Hudson Bay territory
- 1854 - severe epidemics of measles in Tasmania
- 1875 - severe epidemics of measles in Tierra del Fuego
- 1883 - severe epidemics of measles in Fiji

Irrigation increased the population density and enabled the spread of respiratory and fecal-oral viruses i.e. measles, smallpox, cholera, etc.

BUBONIC PLAQUE

The Bubonic Plaque ravaged Europe between 1340 and 1750. It was one of the worst epidemic afflictions in all of human history. One-quarter of the population of Europe died during its greatest prevalence. 30,000 people died in 1 month in London. The poor were more likely to die than the rich. The plague was thought by many to be God's wrath upon sinners. Its origin was determined to be the flea of the black rat. The actual end of the plague in 1750 was the appearance of the aggressive brown rat in cities that avoided humans, had fleas that were less effective carriers and drove most of Europe's black rats out of the urban areas. The development of improved housing and sanitation also contributed to the demise of the plague.

"So lethal was the disease that cases were known of persons going to bed well and dying before they awake, of doctors catching the illness at the bedside and dying before the patient."

Barbara Tuchman, historian

EARLIEST EPIDEMIOLOGICAL STUDY

Sir Percival Pott in England, in 1775, realized chimney sweeps seemed to have a high incidence of cancer of the scrotum. He reasoned the chimney sweep's occupation and close, frequent contact to soot caused the cancer. He suggested the relationship of behavior and a disease of a specific organ. He demonstrated that if behavior changed by increasing bathing, the incidence of cancer could be reduced.

FOUNDATION OF MODERN EPIDEMIOLOGY

John Snow, in 1854, was an English physician who plotted the geographic location of all reported cholera cases in London. He inquired about what they ate, drank, where they went and their activities. He suspected cholera was transmitted by contaminated water since the common factor in the daily lives of the victims was getting water from the Broad Street pump. He closed

the pump and ended the epidemic. He established a mode of investigation, but also demonstrated that research could lead to positive action.

THE GERM THEORY

Recognition resulted in the latter part of the 19th century that bacteria were the source of infection in the human body. This theory served as a precursor to the scientific determination that people come into contact with a variety of causal agents.

DEFINITION OF CAUSAL AGENT

A causal agent can be any organism, substance or a force, the excessive presence or relative lack of which is the immediate or proximal cause. It may change its antigenic character and/or adapt to a new reservoir. For many diseases, the agent may not be recognized.

CLASSIFICATION OF CAUSAL AGENTS

Causal agents may be classified in the categories listed below.

1. Biological - largest group = invading living organisms i.e. parasites, bacteria, viruses, fungi or insects.
2. Nutritional - lack or over abundance of a specific food substance i.e. fats and carbohydrates as producers of cholesterol.
3. Chemical - gases and toxic chemicals (poisons), allergens that pollute the air, water and land and arise outside the host.
4. Physical - fire, sunlight, climate, vegetation, etc.
5. Physiological - events or changes in normal life span can give rise to specific disease conditions i.e. morning sickness during pregnancy.
6. Psychic - common situations in which psychic factors play a role are headaches, nausea, vomiting, hypertension, etc.
7. Genetic - various diseases ranging from point mutations to chromosomal anomalies.

DISEASE AND MODERNIZATION

As societies became more modern, the disease pattern and life styles changed.

Changing patterns of disease in industrialized societies included heart disease, cancer, mental disorders, stroke, and accidents.

Three examples of the effect of modernization are listed below.

Hong Kong:

Early 1950's - The major causes of death were infectious diseases.

From 1951 - 1989, there were better health services and improved socioeconomic progress.

Infant mortality decreased from 91.8 to 7.4 per 1,000 live births; life expectancy increased to 72 years of age for males and 78 for females; leading causes of death now related to aging, not infection.

Nigeria:

Mid 1980's - Due to an oil boom, Nigeria had the world's highest mortality rates from automobile accidents; increased environmental pollution; decreased health disorders relative to stress and increased smoking and lung cancer.

Jamaica:

1920 - Jamaica had a level of health similar to that of the poorest country in Africa.

1945-1970 - Development occurred which resulted in decreased mortality from infectious disease (principally TB & syphilis); decreased parasitic disorders (mainly malaria); declines in GI and respiratory disease; life expectancy increased from 53 to 68 years of age; infant mortality dropped from 90 to 32 per 1,000 live births; and death rates increased for cancer & diseases involving the heart and nervous system.

CUSTOMS, HABITS AND BELIEFS

Customs, habits and beliefs can influence the evolution of disease in various societies. Some of these are listed below for your information and clarification.

1. Food storage and preparation may influence the prevention of botulism and GI distress.
2. Agricultural practices of sharing housing with animals promoted zoonoses.
3. Ritual cannibalism. i.e. Fore people in New Guinea acquire Kuru (a chronic progressive disease of the CNS due to a virus) due to the custom of butchering, cooking and eating a dead kinsman as part of their mourning ceremony.
4. Contact with religious articles/objects may transfer infectious objects between individuals.
5. Circumcision - Jewish women have low rates of cervical cancer relative to non-Jewish women in the U.S.
6. Consanguineous marriage (descendant of the same parent or ancestor) may promote undesirable genetic abnormalities.

SOCIAL ENVIRONMENT AND DISEASE

Actual living conditions such as poverty, overcrowding, and also the norms, values and attitudes that reflect a particular social and cultural context can influence disease prevalence. Societies have socially prescribed patterns of behavior that provides information to identify causal agents, trace the transmission process, and ascertain most effective means of treatment and prevention within a particular environment.

DIET AND DISEASE

There is absolutely no question that diet influences the prevalence of particular diseases. Hjermann & Associates, in 1981, determined that eating less fat or cholesterol can reduce the chances of a heart attack or sudden death from heart disease. They began the study in 1972 of 1,232 men 40-49 years of age who had high cholesterol and 80% of whom smoked. He provided them a new diet in which they were instructed to substitute skim for whole milk; eat no more than one egg per week; use polyunsaturated oil for cooking; have fruit for dessert; make sandwiches from high fiber breads with fish or low fat cheese or meat; use fish or low fat meat with potatoes and vegetables for main dishes; and no drugs used, no exercise, no weight loss.

By 1977, 13% had lower cholesterol, the rate of protective high-density cholesterol had risen and 47% had a lower risk of heart disease than the control group.

EXERCISE AND DISEASE

It has been shown conclusively that the type and amount of physical exercise throughout life can be a predictable factor for certain diseases.

Ralph Pafferbarger and Associates investigated the physical activity and lifestyle characteristics of 16,936 Harvard University alumni aged 34-74 years of age for a period of 12-16 years. Exercise was considered walking, climbing stairs, and playing moderately vigorous sports. Life expectancy improved for all causes of mortality, especially coronary heart disease.

AGE AND DISEASE

Improved medical care, nutrition, sanitation and housing have combined in the 20th century to help promote longer lives for most Americans.

1900 - life expectancy was 47.3 years of age
1990 75.4 years+
2050 - 21.8% of the population will be over 65 years of age

Senior citizens are healthier, better educated and more affluent than any other elderly group in history! They possess increased political power and increased needs for health services.

About 1 out of every 3 U.S. Presidents has lived to enjoy a normal life expectancy!

WORK AND DISEASE

When occupational hazards are added, men are at greater risk of developing major degenerative diseases than women. Industrial lung diseases from both mineral and organic substances promoted pneumoconiosis. Middle-aged professional men in the U.S. are considered a high-risk group according to life insurance companies due to stress-related illnesses.

SEXUAL PRACTICES AND DISEASE

Different populations of people have had either increased or decreased prevalence of syphilis, gonorrhea and AIDS over the decades of history.

GENDER AND DISEASE

In pre-industrial societies, the life expectancy of men and women was approximately the same. In the 20th century, life expectancy has increased for both men and women, but women live longer on the average than men. Men die from heart disease, cancer, cerebrovascular accidents, pneumonia while women suffer from more frequent illnesses and disabilities, but eventually die from the same causes.

Men have 2 distinctive disadvantages over women:

#1 biological - pyloric stenosis, hyaline membrane disease, and certain circulatory disorders are greater in men at birth.

#2 social/psychological - more aggressive nature allows them to sustain more and serious accidents and injuries.

In 1993, The National Center for Health Statistics found that women have increased rates of acute illness i.e. infectious, parasitic, GI and respiratory conditions as opposed to men.

Women have increased rates of hypertension, thyroid, anemia, GB conditions, chronic enteritis and colitis, migraines, arthritis, diabetes, and urinary system diseases. Men have increased losses of limbs, gout, emphysema and heart disease.

Summary:

Women are more fit biologically, less often exposed to danger and highly stressful occupations, are more sensitive to their bodily states and use medical services more often than men.

Depression and anxiety are more prevalent in women than men. Overall, men are 1.5 x more likely to die from cancer than women.

SOCIAL CLASS AND DISEASE

Medical systems in the U.S. have not been designed to meet the needs of the poor. While income and occupational status are important, the strongest single predictor of good health appears to be education. Well-educated people are generally the best informed about the merits of a healthy lifestyle and the advantages and availability of early medical intervention.

Regardless of gender, persons living in poverty and reduced socioeconomic circumstances have greater exposure to physical, chemical, biological and psychological risk factors that produce ill health than more affluent individuals.

RACE AND DISEASE

Asian Americans are the healthiest racial group in American society. Asian Americans have typically enjoyed higher levels of health while Blacks, Hispanics and Native Americans have significant disease impact relative to Whites.

Blacks experience decreased life expectancy, increased prevalence of AIDS, cancer, heart disease, diabetes and hypertension. Hypertension kills 15 times more Blacks than Whites — with the exact cause unknown.

Hispanic Americans are the fastest growing minority group in the 21st century. Hispanics experience increased stomach cancer, diabetes, hypertension, TB, lung cancer, alcoholism and homicide. The prevalence of these diseases is attributed to poverty, lack of education and restricted access to healthcare.

Native Americans have improved their level of health in the last 40 years. Native Americans experience the lowest rate of cancer in the U.S., but have an increased mortality from diabetes, heart disease, strokes, influenza and suicide (20% higher than the general population). Native Americans have the highest death rate from automobile accidents than members of any other racial group in the U.S. and an exceptionally high prevalence of alcoholism.

THE EVOLUTION OF MAN

The evolution of man has mystified and intrigued members of a variety of scientific communities for many decades. It has been collectively agreed that man has evolved through the process of adaptation. Adaptation is defined as a long-term change process or complex of processes that affects a population within its environment. These processes can be genetic, cultural and developmental. Through adaptation, chances of survival are increased.

The pre-Darwinian evolutionists viewed evolution as a literal interpretation of the Bible's Book of Genesis. There was a single creation of the earth and living things by God. Linnaeus classified all living things in order to better understand the Creator's plan. This classification is called taxonomy and is provided on the next page for your reference. Mayar come to the conclusion that there exists a "ladder of perfection" which fits neatly into God's plan. This "ladder of perfection" related to the lower and upper levels of living things relative to their physical and mental capacities. In later decades the pre-Darwinian evolution theory, catastrophism was developed in which they believed multiple creations occurred with man maintaining a superior place in the natural order of living things.

The Darwinian Era began in 1859. Charles Darwin and his followers proposed the theory that the species evolved through the operation of natural selection and natural variation. Evolution was initiated by the effects of mutation that supplied new genetic variations that increased or decreased the level of fitness for survival. Natural selection was theorized to preserve variations that provided the greatest level of survival fitness. This particular theory continues to prevail.

Non-Darwinian evolutionists believe that evolution resulted from random forces operating on some central genetic variations.

Regardless of which evolutionary theory you have an affinity to, there is no question that man has been compared to mammals and primates. The correlation of man to mammals involves the development of internal fertilization and gestation that insured greater survival of offspring, the presence of four limbs and the five digits on each limb provided adaptive value in survival. When comparing man to primates, both species have opposable thumbs, stereoscopic color vision, eyes on the same frontal plane, enclosed bony eye orbits, large brain relative to body size and three kinds of teeth (incisor, premolar and molar). Bipedalism is defined as walking on two feet. The evolutionary process of utilizing four limbs to two provided opportunities to develop the upper limbs for locomotor activities, to accommodate child rearing, to develop tools, and to begin the early process of manufacturing. Bipedalism has been estimated to occur between 12-20 million years ago.

There have been some major archeological finds relative to the discovery and speculation of the evolution of man. The People of the Lake, discovered by Leakey and Lewin in 1978, have been estimated to be 2.5 million years old. These remains were found at Lake Turkana, in Kenya. In studying the remains, it was determined that the males served as scavengers for immature or lame animals to be used as a food source for protein. Wooden tools were discovered at the site in addition to remnants involving the community activity of food sharing.

Donald Johnson found fossilized partial remains of ten or more hominids (human-like animals) in a single site in Ethiopia.

The People of the Plateau were discovered in 1888 by workers digging a ditch for a water main in Torralba and Ambrona in north central Spain. These remains have been estimated to be 400,000 B.P. In 1966, Clark Howell excavated this area more extensively and found human habitation sites, places for butchering animals, bifacial stone tools, and cooking utensils. He also came to the conclusion by the location and arrangement of remains that there existed a social and economic organization within this population who utilized seasonal encampments. He speculated that rituals occurred based on the orderly alignment of elephant bones with cranial vaults smashed open to extract and eat the brain.

The People of the Cave were discovered in 1960 by Ralph Solecki and have been estimated to be 60-100,000 years old. The Shanidar Cave is located in Northern Iraq and contains the remains of nine individuals. Pollen was also found in the surrounding soil that indicated that this may have been a gravesite in which flowers and herbs of medicinal value were utilized to save the victims. Ritual feasts based on the remains from animal bones probably occurred at that site and under those circumstances. Some investigators feel a rock fall in the cave may have led to the demise of the nine individuals.

The Bog people of the Iron Age were found intermittently over the centuries in Denmark's peat bogs. During the past 200 years, more than 150 men, women and children have been uncovered. These remains of human corpses have been well preserved because of the constant action of moderately ascetic bog water that acted as a preservation media. Two discoveries dramatically served to bring the Bog People a share of international anthropological acclaim in the early 1950's. The "Tollund Man" was named for the bog in which the peat diggers discovered his remains. He lived approximately 2,000 years ago. The soft tissue of his flesh, particularly in the face, abdominal region and feet, was so well preserved that wrinkles and pores could be seen. The stubble of a beard was also found on his chin. His hair was approximately two inches in length. Of particular interest was the plaited skin rope found tied in a slipknot around his neck.

A team of medical and anthropological experts concluded that he had died by hanging. The second find was the "Grauballe Man" who was uncovered near the village of Grauballe located 11 miles east of the Tollund find. Perfect fingerprints were obtained from the right hand and most of the flesh and bones were remarkably well preserved. This man probably lived between 200 and 400 A.D. The Grauballe Man had been killed by having his neck cut from ear to ear. The preserved skin revealed the evidence of more than one stroke of a cutting implement. Combining this paleopathological evidence, a fairly complete picture of the Iron Age population has been reconstructed. An ancient highway used by pilgrims traveling from Iceland to Rome passed through the region. Peat was used for fuel 20 centuries ago just as it is today. Although meat played a role in diet, the analysis of the intestinal remains of the two men indicated that wild grass, weeds and cultivated grains were prominent. In fact, 63 different types of grain, grass and weeds were represented which leaves investigators to believe that small fields of grain were tended in the open areas.

Because of these and other archeological finds, it has been determined that the earliest members of humankind were distributed in Africa, Asia and in Europe.

THE TAXONOMIC POSITION OF HUMANKIND

Taxonomy is the array of all life forms classified in progressively narrower, more restrictive categories.

Health, disease and illness are part of the evolutionary process of how the human species relates to other living things in the natural world.

Kingdom: Animalia

Phylum: Chordata — all animals with a tubular nerve cord running down the spinal or dorsal surface.

Class: Mammalia — animals that produce milk from mammary glands, maintain constant body temperature, have hair and have a single bone in the lower jaw.

Infraclass: Eutheria — develop placenta to nourish the fetus during gestation.

Cohort: Unguiculata — have nails instead of claws and four limbs.

Order: Primates — "first order", high degree of dexterity, a larger brain, and in many cases, more means of adaptation.

Suborder: Anthropeida — possessing juvenile and adult sets of dentition and hemachoroid placenta

Family: Hominidae — no tail and terrestrial bipedalism as locomotion

Genus: Homo — made tools and rely on culture.

Species: Sapiens — approximately the same large brain size.

HUMAN POPULATIONS AND DISEASE PROMOTION/PREVALENCE

Let's investigate the development of five major human populations throughout centuries who have made definite contributions to our current knowledge of disease manifestations and who we have become today.

POPULATION #1:

In the beginning...Hunter/gatherers (East Africa, Southeast Asia and Australian desert)
Time period: 5 million - 12,000 years ago.

SOCIAL ECOLOGY

The earliest history of man possessed the following social interactions:

- Small nomadic bands of 20-50 people with kin groups of 1-5 families;
- dialect tribes interacted as a group of 500 people sharing the same language, religious rituals, marriage ceremonies, etc.;
- intense use of natural resources in environment without damage i.e. no pollution, killing, etc.;
- population density = 1 person per square mile;
- too large a group meant expanded area to search for food and physical labor;
- groups over 50 promoted internal stress/tension and began to split up due to food shortages, peer review, etc.;
- small groups of "friends" for psychological support.

DISEASE PATTERNS

The disease patterns of early man followed in these patterns and categories.

- tropical ancestors from East Africa so temperature limited propagation of certain diseases;
- vectors couldn't survive the climate easily;
- epidemic diseases did not exist because:
 - a. size of social group too small
 - b. small bands were isolated geographically before they could pass on disease to another band; low contact = got immune or died off before seeing another band

-Disease group #1 Primate

head lice, pinworms, intestinal protozoa, bacterial diseases, "sleeping" sickness, and yaws/pinta (children with benign syphilis)

Disease group #2 Zoonoses (exposed to animal pathogens)

insect bites/puncture wounds, rabbit fever, ticks carrying 50 viral diseases, tapeworms from raw flesh eating didn't claim many victims - severe impact on body adults were affected more so than children limited contact dependent on animal travel patterns

Disease group #3 Latent Viral (chronic)

shingles/herpes and post polio syndrome

Disease group #4 Skin Infections

fungi infections from soil, bruises and abrasions

Disease group #5 Unknown (diseases which became extinct)

TB may have evolved from leprosy historically

Disease group #6 Little or No Degenerative

lot of exercise, no refined foods, traumatic arthritis, general wear & tear and hereditary implications

NUTRITION PATTERNS

Earliest man followed the nutritional patterns identified below.

- no nutritional deficiencies due to small populations easily fed;
- great variety of abundant food supply based on the season;
- omnivore with a tendency to vegetarian;
- used 5x less salt than today;
- used 50% less polyunsaturated fat than today;
- no refined carbohydrates (sugars) used honey;
- wild game has less fat content than domesticated animals;
- more vitamin C/K/Calcium and fiber;
- 2 to 5 x more protein;
- mother's milk only dairy product (high cholesterol content which may stimulate anticholesterol agent and immunity.

HEALTH PROFILE

The health profile of early man indicates the following:

- satisfactory longevity;
- high childhood mortality;
- low blood pressure;
- low dental decay;
- high exercise variety;
- less stress;
- hearing better though a less noisy environment than today.

POPULATION CONTROL

Population was controlled under the following conditions.

- no overcrowding due to infanticide and abortion which allowed control of physical defects and selectivity;
- 15-50% of pregnancies terminated;
- 3/4 family members with 4 year gaps between siblings;
- postpartum taboo on intercourse during the breast-feeding time period (contraceptive effect);
- reduced body fat reduces ovulation cycles.

POPULATION #2:

Next came the Village Food Producers (start of farming and agricultural systems in southeast Asia/Thailand)

Time period: 12,000 to 5,000 years ago

Hunters switched to farming because climate and food patterns changed to grow crops and population pressures due to larger numbers.

SOCIAL ECOLOGY

The social interactions of early man were changed in the following manner.

- clusters of farms in villages with concentrated groups of 600-800 people;
- less mobile;
- need to commit labor to project to get rewards (raising crops to get harvest);
- begin to get feelings of personal property and ownership rights;
- defining group identification i.e. inheritance, civil laws/rules/dissent; tension between groups competing for property and trade;
- decisions required between families or groups rather than relatives.

DISEASE PATTERNS

Disease patterns changed from hunter/gatherers to Village Food Producers due to several factors:

- larger number of people in a small area created waste disposal, sanitary water supply problems;
- increased number of bowel to mouth diseases i.e. cholera, hepatitis, dysentery;
- increased vector concentrations i.e. flies to contaminate food, vermin in housing areas, and parasites establish themselves;
- poor air circulation in houses with animals in residence i.e. hookworm, toxoplasmosis, tetanus, etc.;
- porous pots for cooking generated disease;
- ingested infected food products i.e. bovine TB from contaminated milk or undulant fever from infected raw milk;
- person-to-person transmission of disease from animal sources i.e. measles from cows, influenza from chickens and pigs, colds from horses, etc.
- agricultural practices altered the environment to encourage disease by:
 - a. irrigation ditches - increased malaria (major killer) shistosomiasis (snail contains liver flukes & enters pores of skin (major debillatator)
 - b. feces fertilization
 - c. forest clearance - destroyed major animals who were hosts before now transferred to humans and eliminated natural enemies i.e. rats eaten by snakes and hawks, etc.
 - d. flattened areas made puddles for malaria propagation
 - e. trading between villages and regions transferred diseases and immunity.

NUTRITION PATTERN

Nutritional habits changed from hunter/gatherers to Village Food Producers due to:

- more food propagation;
- diet changed with less variety (based on selected crops);
- nutritional crops chosen may have missing elements (nutritional deficiencies);
- new diseases became apparent i.e. beriberi (low B-1), pellagra (low niacin), scurvy (low vitamin C) until vegetable crops were mature;
- starvation episodes due to crop failures;
- farmers had anxiety about food supply annually.

POPULATION CONTROL

Village Food Producers controlled the population based on these conclusions.

- high infant mortality due to weaning diarrhea (protein deficiency and unsanitary conditions);
- population surged due to:
 - relaxed need for child transport
 - children became economic asset so spacing between siblings shortened
 - kin groups could serve as babysitters while parents worked in fields
 - more total food provided more body fat on women that allowed younger women to become fertile earlier i.e. 13/14 vs. 18/19 years of age
 - wean infants earlier because softer foods became available i.e. cereals
 - breast-feeding contraceptive less effective

POPULATION #3:

Pre-Industrial City Population (occurred in Middle East first)
Time period: 5,000 years to 1600's

ERA OF URBANIZATION

Agricultural centers for trading, religious and political centers, coastlines and overland trade routes provided the opportunities for urbanization.

SOCIAL ECOLOGY

The Village Food Producers evolved into the Pre-Industrial City population because of:

- greater specialization of occupational trades;
- social stratification occurred based on ranking and income differences;
- development of empires;
- colonization of small areas.

DISEASE PATTERNS

Disease patterns changed for the Pre-Industrial City population because of the following conditions:

- same as villagers, only more intense due to the increased number of people and wastes;

- childhood "crowd" diseases manifested i.e. needed 300-500,000 individuals to keep measles and smallpox active;
- no animal hosts - all person-to-person transmission;
- major epidemic periods with major suffering i.e. plague, yellow fever, malaria killing off peasants and feudal system;
- age of discovery at end of this period (Columbus finds New World, Portuguese explore African coast, Dutch, British, French, Spanish and Swedes explore North America) which created opportunities for U.S. and Europeans to exchange diseases i.e. yellow fever and malaria from slave ships from Africa;
- 1490-1890 = 90% of the North American Indians were dead due to lack of education on how to deal with European diseases and 1 million Jamaicans died in a 70 year period;
- some diseases were promoted for the purposes of eradication i.e. give smallpox infected blankets or leave infected person in a crowd, etc. (earliest known biological warfare).

NUTRITION PATTERNS

The Pre-Industrial City people had their nutritional pattern changed.

- peasant class tied to the land and susceptible to periodic famines and wars;
- very diverse food for wealthy people;
- very narrow, monotonous food variety for poor people; meals/portions served in order of priority i.e. father/worker 1st, children next and mothers last;
- vitamin deficiency diseases in urban poor; increased death rate from infection and malnutrition.

POPULATION CONTROL

The Pre-Industrial City population controlled their numbers based on these factors.

- longer life expectancy in upper class;
- elitist lived better; -colonists healthier than colonized;
- redistribution of people resulted due to a loss of men from wars and disease.

POPULATION #4:

Agri-Industrial Population (Industrial Revolution)

Time period: 1650 - World War II

SOCIAL ECOLOGY

The social interactions of the Agri-Industrial population can be divided into two parts.

Part 1 = Beginning of the Era

- very poor living conditions for the masses i.e. overcrowding, poor sanitation, poor housing, contaminated water sources, and marginal nutrition;
- tremendous migration from rural to urban areas due to steady source of employment based on steady recruitment to work in factories;
- great empires continued to expand.

Part 2 = Conclusion of Era 1900's

- improved environment;
- rise of labor movement i.e. unions to improve living and working conditions;
- rebellion - can't keep the poor suppressed;
- improvements in medical care delivery;
- increasing affluence due to increasing purchasing power.

DISEASE PATTERNS

The disease patterns for adults and children changed from the Pre-Industrial City population as follows:

- increasing numbers of infections, sanitary and industrial diseases, i.e. rickets, black lung, etc.;
- increased air and water pollutants based on industrial needs;
- battles over worker's compensation;
- increased number of immigrants with few rights, and little communication skills or social value;
- "crowd" diseases continue;
- stress on children due to labor needs;
- imperialistic expansion which spread disease by explorers and slavery;
- advent of medical doctors who entered work environment to keep workers healthier.

NUTRITION PATTERNS

Dietary needs and the propagation of food changed in these 300 years as listed below.

- diets changed because they ate what they could afford;
- diets diversified and improved in manufacturing urban areas in Europe;
- diets declined in the colonies - farmland converted to cotton and sugar plantations;
- colony populations raised food to support mother country.

POPULATION CONTROL

The growth of the population changed during this time period.

Prior to mid-1800's there was decreased mortality and increased fertility

After 1850's there was decreased mortality and decreased fertility because children were expensive in the city. They were of no value to labor until 10-12 years later.

Large families limited job mobility and economic wealth.

There was a decline in personal wealth.

Male contraceptives/co-operation was prevalent such as withdrawal and rhythm.

OUR CURRENT POPULATION:
Techno-Industrial /Modern Population
Time period: World War II to Present

SOCIAL ECOLOGY

Our interactions on a personal level changed. The last 50 years are considered a cultural watershed in medicine, chemistry and biology. Manufacturing and techniques were applied to civilian life from military applications with mass marketing. During peace times, there was high gear production for war. The development of a throwaway, competitive society became predominant.

DISEASE PATTERNS

Six categories emerged based on the redistribution of the population:

1. *Infectious disease*

successful programs of prevention and control due to antibiotics, sulfa, immunizations;
new diseases appear i.e. Legionaire's, AIDS, new varieties of TB, etc.
drug resistant virus/germs that maximized reproduction potentials;
rapid travel and world exchange of people.

2. *Chemicalization of the Environment*

- a. home = cleaning agents, additives and preservatives in food and insecticides
- b. work = some are lethal, but not successful due to corporate interference, worker ignorance/apathy or medical indifference

3. *Community*

pollutants i.e. industrial and personal such as smoking 50-80% cancers may be environmentally induced genetic consequences not available yet since seven generations are needed to see/study people

4. *Mental Illness*

stresses of life i.e. breakdown of traditional social structure such as family, church, marriage, etc.

5. *Greater Longevity for Greater Number*

more chronic diseases with years of asymptomatic changes on a limited economic income;
associated years of supportive care;
more cultural problems i.e. loneliness, depression, etc.
early detection important to slow decline

6. *Higher Incidence of Iatrogenic Disease*

result of being treated for a disease
poor surgical work/human error
poor equipment
accidental byproduct of drug therapy
20% of hospital admissions acquire disease

7. ***Widening Gap between Social Classes in Medical Care***
greater degrees of custodial care needed;
existence of physical, mental, medical and financial abuses;
limited availability of home healthcare and social services;
racism;
poverty;
more geriatricians/nurse geriatric specialists needed;
no national health insurance

NUTRITION PATTERNS

Tremendous concern for nutrition developed in the last 50 years. Examples included:

- food fads i.e. loose weight, reduce aging, reduce cancer risk;
- lack of concern by medical profession; perpetuation of commerciogenic malnutrition i.e. highly processed/artificial foods or mixed foods;
- malnutrition of homeless and poor.

POPULATION CONTROL

Baby boom after World War II created a big population surge and overbuilt schools.

Economic hard times with recessions occurred.

A decline in family size in the 70's resulted with the advent of the "pill".

Population groups became smaller i.e. Catholics smaller due to aging older members who held traditional values.

Senior citizens as the "gray" lobby affect legislation.

There exists increasing Third World populations and animosity to the U.S. economy.

There exists ongoing international wars of varying intensity.

CONCLUSION OF RISK FACTORS FOR ILL HEALTH IN MODERN SOCIETY

Demanding lifestyles, inadequate diet, smoking, drug and alcohol abuse, obesity, lack of exercise, and exposure to environmental pollution have all been identified as major influences to modern societies. The good news is most of these contributing factors can be managed effectively by changing lifestyles. Even though educational emphasis has been placed on these factors, Americans repeatedly fail to follow a more favorable, health-promoting environment, socially, economically, and/or physiologically.

COMPARISON OF LIFESTYLES FOR ANCIENT VS. MODERN MAN

Late Paleolithic Lifestyle

Contemporary American Lifestyle

Genetic make up of humans has changed little in the last 10,000 years. Current humans are still late Paleolithic pre-agricultural hunter/gatherers genetically only!

minimal housing, sanitation and medical care

improved housing, sanitation and medical care

reduced life expectancy

doubled life expectancy

increased exercise and stamina

decreased exercise and stamina

increased protein 34%

decreased protein 12%

decreased sugar

increased sugar

increased K, decreased Na

decreased K, increased Na

little alcohol use

increased alcohol use

little tobacco use

increased tobacco use

increased infant mortality

decreased infant mortality

increased infectious diseases

reduced infectious diseases

decreased calories

increased calories

decreased diabetes

increased diabetes

decreased Ca

increased Ca (70-90% result from environmental factors)

65% vegetables and fruits; 35% meat

increased meats/limited vegetables and fruits

lived in semi-tropical climate

multi-climate environments

This concludes unit 15. Please proceed to the unit questions and complete the required personal data.

Some Important Terms and/or Concepts in Unit 15

Medical Anthropology is the study of disease in past and present day human populations, which provides insight into the relationship between people and their environment.

Disease may be defined as an "impairment of health and well-being".

Disease occurs when the organism is not functioning in equilibrium.

An epidemiologist is an individual concerned with exploring human ecology as it relates to the health of human beings and their environment.

Paleopathology is the science of diseases that can be demonstrated in ancient man and animals.

The host is an organism that provides a nutritional environment for another organism. The agent is the invading organism or cause of a disease.

The human body has several lines of defense to prevent infective agents from causing disease:

1. intact skin and mucous membrane to resist penetration;
2. functional i.e. coughing to rid respiratory passage of harmful substance;
3. pain, touch, smell, taste, sight and hearing to activate an evasive action if danger threatens;
4. immunological response of antigens and the production of protective antibodies.

Contact with vectors or organisms shows several patterns relative to the season and the level of transmission.

When human beings lived as nomads or in widely scattered and isolated communities, the danger of epidemics and infectious disease was slight.

Crowding in primitive cities with unsanitary living conditions and an abundance of rats and lice increased the risk of developing communicable diseases because diseases could spread more quickly and the disease-causing micro-organisms would persist within a community for longer periods of time

Migration of peoples from one region of the world to another spread a disease for the first time.

The Bubonic Plaque ravaged Europe between 1340 and 1750. It was one of the worst epidemic afflictions in all of human history.

Sir Percival Pott in England, in 1775, suggested the relationship of behavior and a disease of a specific organ.

John Snow, in 1854, was an English physician who established a mode of investigation.

A causal agent can be any organism, substance or a force, the excessive presence or relative lack of which is the immediate or proximal cause.

Changing patterns of disease in industrialized societies included heart disease, cancer, mental disorders, stroke, and accidents.

Customs, habits and beliefs can influence the evolution of disease in various societies.

Actual living conditions such as poverty, overcrowding, and also the norms, values and attitudes that reflect a particular social and cultural context, can influence disease prevalence.

Diet influences the prevalence of particular diseases.

The type and amount of physical exercise throughout life can be a predictable factor for certain diseases.

Improved medical care, nutrition, sanitation and housing have combined in the 20th century to help promote longer lives for most Americans.

When occupational hazards are added, men are at greater risk of developing major degenerative diseases than women.

Different populations of people have had either increased or decreased prevalence of syphilis, gonorrhea and AIDS over the decades of history.

In the 20th century, life expectancy has increased for both men and women, but women live longer on the average than men.

The strongest single predictor of good health appears to be education.

Hunter/gatherers (East Africa, Southeast Asia and Australian desert). Time period: 5 million - 12,000 years ago.

Village Food Producers started farming and agricultural systems in southeast Asia/Thailand. Time period: 12,000 to 5,000 years ago.

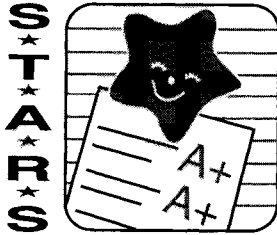
Pre-Industrial City Population occurred in Middle East first. Time period: 5,000 years to 1600's.

Agri-Industrial Population (Industrial Revolution). Time period: 1650 - World War II.

Techno-Industrial /Modern Population. Time period: World War II to Present.

Demanding lifestyles, inadequate diet, smoking, drug and alcohol abuse, obesity, lack of exercise, and exposure to environmental pollution have all been identified as major influences to modern societies.

Americans repeatedly fail to follow a more favorable, health-promoting environment, socially, economically, and/or physiologically.



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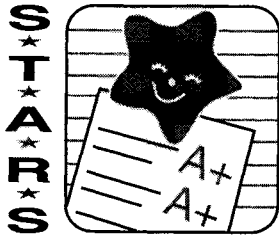
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UNIT NUMBER 16

ETHICS OF HUMAN RADIATION EXPERIMENTS

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INTRODUCTION

In this unit we will review some basic concepts of informed consent, the legal cases that improved safety of patients, the discovery and government acknowledgement of human radiation experiments and the recommendations of policy formation protecting patients from unethical situations involving radiation in the next millenium.

This unit is a part of a continuing education program for Radiographers and General X-Ray Machine Operators. This unit is not valid for continuing education credit without a certificate signed by an official from S.T.A.R.S.

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HISTORICAL CONTEXT

Since the discovery of x-rays and radioactivity, radiation has been used to:

understand bodily functions;
diagnose disease; and
treat cancer.

Within the same 100 years of discovery, the perils of overexposure to radiation were becoming apparent. During World War II, the new field of radiation science was at the center of one of the most ambitious and secret research efforts the world has known—The Manhattan Project. Human radiation experiments were undertaken *in secret* to help understand radiation risks to workers engaged in the development of the atomic bomb.

ATOMIC ENERGY COMMISSION

Created after World War II, the AEC used nuclear weapons facilities to produce radioisotopes for medical research and other peacetime uses which provided the bases of *thousands* of human experiments in the United States and the world.

The AEC research was part of a larger postwar transformation of biomedical research through the infusion of substantial government monies and technical support. The intersection of government and biomedical research brought with it new roles for researchers and new ethical questions. Many medical researchers were also physicians who operated within the tradition of medical ethics that enjoyed them to put the interests of their patients first. When a doctor was also a researcher, the potential for conflict emerged between the advancement of science and the advancement of the patient's well-being. Medical researchers were called on by government officials in the development and testing of nuclear weapons i.e.

provide human research data that could assure officials about the effects of radiation and restrict discussions/debate on their results with other members of the scientific community.

News of the Cold War radiation experiments were developed in a series of articles in the Albuquerque Tribune in November, 1993. Eileen Welsonce won a Pulitzer Prize for reporting the discovery of code names for identification of human subjects while researching information on animals and radiation.

Secretary of Energy Hazel O'Leary was determined to make public information about the experiments. Her department had its origins in federal agencies that had sponsored plutonium experiments and were responsible for the development of nuclear weapons.

Documents dated April 17, 1947 from the Corps. Of Engineers to the United States Atomic Energy Commission, reads:

"1. It is desired that no document be released which refers to experiments with humans and might have adverse effect on public opinion or result in legal suits. Documents covering such work field should be classified "secret." Further work in this field in the future has been prohibited by the General Manager. It is understood that three documents in this field have been submitted for declassification and are now classified "restricted." It is desired that these

documents be reclassified "secret" and that a check be made to insure that no distribution has inadvertently been made to the Department of Commerce, or other off-Project personnel or agencies.

"2. These instructions do not pertain to documents regarding clinical or therapeutic uses of radioisotopes and similar materials beneficial to human disorders and diseases."

This document confirms the fact that the United States government conducted experiments that had no clinical or therapeutic value and classified them as secret in fear of adverse public opinion and/or litigation. It was not declassified until February, 1994.

PATIENT CONSENT

Patient consent is based on the principle of **autonomy** (every individual has the right to determine his or her own destiny). It provides a *contract that gives health care professionals the right to touch and treat the patient.*

There are three essential concepts involved in the principle of informed consent.

1. **Communication** — must tell the patient what he/she needs to know to decide the best course of treatment;
2. **Law** — legal rights in the consent process established through guidelines and court cases;
3. **Ethics** — concepts such as beneficence and autonomy

There are three types of consent.

1. **Simple** — patient verbally or by action agrees to have a procedure performed;
2. **Express** — to put thought or opinion into spoken or written words;
3. **Implied** — occurs in emergency situations when the patient cannot decide with a reasonable- person standard most often would use.

Informed consent involves the patient's ability to fully understand the following items:

- a. the nature of the procedure
- b. the risks involved, including side effects and complications
- c. desired outcomes of the procedure
- d. possible alternatives

The legal capacity to give consent is determined if he or she is a/an:

- a. competent adult
- b. legal guardian or representative of an incompetent adult
- c. emancipated, married or mature minor
- d. parent or legal guardian of a child
- e. individual obligated by court order

When informed consent is *not* obtained, the legal consequence is *battery* (actual act of harmful or unwarranted or unconsented contact with a person);

When informed consent is *deficient or inadequate*, the charge most often brought is *negligence* (breach or failure to fulfill the expected standard of care).

HISTORICAL PERSPECTIVES

The following cases provide the development and evolutionary process of informed consent.

1914 — UNITED STATES SUPREME COURT

Schloendorff case — Judge Cardozo's decision:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and the surgeon who performs an operation without his patient's consent commits an assault for which he is liable for charges."

LATE 1940'S — NUREMBERG CODE

Designed after World War II when the Nazi and Japanese medical experiment atrocities were recognized, the code provided the guidelines for considerations such as informed consent, value as benefit to society, avoidance of unnecessary injury and suffering, conduction by scientifically qualified persons, termination of the experiment, etc.

1957 — SALGO VERSUS LELAND STANFORD UNIVERSITY BOARD OF TRUSTEES

"A physician violates his duty to his patients and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed therapy."

1972 — CANTERBURY VERSUS SPENCE

*The patient **must be given** information that indicates the **risks, benefits, alternatives and outcomes** of suggested treatments and the **results** if the recommended treatment is not followed.*

1974

The Department of Health, Education and Welfare adopted regulations governing the conduct of all human research it sponsored.

It is considered a watershed year in the history of federal protection for human subjects.

1974 — NATIONAL RESEARCH ACT

Institutional Review Boards (IRBs) must approve all federally-funded proposed research on human subjects.

Problem 1 Most IRB members are colleagues of the individuals doing the research leading to potential conflicts of interest and

Problem 2 There is little incentive **not** to approve a study since research dollars would be lost.

1990/91 — PSDA

The Patient Self-Determination Act mandates that healthcare institutions receiving Medicare and Medicaid funding provide written information about patient's rights to participate in medical decision making and the formulation of advance directives.

RECENT — ARATO VERSUS AVEDON

California Supreme Court affirmed the process of informed consent as information sharing with the patient making the decision and the physician serving as the fiduciary (one who handles the affairs of another).

The element of trust is implied and if the trust is violated, the physician is liable.

THE PRESIDENT'S ADVISORY COMMITTEE

President Clinton created the Advisory Committee on Human Radiation Experiments on January 15, 1994 to: *investigate reports about possibly unethical experiments involving human subjects and radiation funded by the government from 1944 through 1974.*

The Advisory Committee was charged by President Clinton to

- a. uncover the history of radiation experiments from 1944-1977;
- b. examine cases in which the government had intentionally released radiation into the environment for research purposes;
- c. identify the ethical and scientific standards for evaluating these events with *recommendations to ensure that whatever wrongdoing may have occurred in the past cannot be repeated.*

The Advisory committee consisted of 14 members:

1 citizen representative and 13 experts in bioethics, radiation oncology and biology, nuclear medicine, epidemiology and biostatistics, public health, history of science and medicine and law.

The President convened the Human Radiation Interagency Working Group composed of:
Secretaries of Defense, Energy, Health and Human Services and Veterans Affairs;
Attorney General;
Administrator of the National Aeronautics and Space Administration;
Director of the Central Intelligence Agency and
Director of the Office of Management and Budget

THE COMMITTEE'S APPROACH

April, 1994 and July, 1995, the Advisory Committee held 16 public hearings mostly in Washington, D.C. and presided over public forums in various cities.

The Advisory Committee heard from more than 200 witnesses and interviewed dozens of professionals who were familiar with experiments involving radiation.

The Advisory Committee created the Ethics Oral History Project to learn from eminent physicians about how research with human subjects was conducted in the 1940s and 1950s.

The Advisory Committee granted unprecedented access to review 100,000 government documents (some potentially important collections could not be located or had been destroyed, largely in the course of routine government operations).

SECRECY AND THE PUBLIC TRUST

The government often *did not create or maintain records*, preventing the public, and those most at risk, from learning the facts in a timely and complete fashion. *The recovered documents identified 4,000 human radiation experiments sponsored by the federal government.*

The *greatest harm* from past experiments and intentional releases may be the *legacy of distrust*. Secrecy was necessary because of the concern for embarrassment to the government, potential legal liability, worry that public misunderstanding would jeopardize government programs, and national security reasons.

CATEGORIES OF EXPERIMENTS

The 4,000 human radiation experiments sponsored by the federal government included:

- plutonium and other atomic bomb materials;
- AEC program of radioisotope distribution;
- nontherapeutic research on children;
- total body irradiation;
- research on prisoners;
- nuclear weapons testing;
- intentional environmental releases of radiation; and
- observational research on uranium miners and residents of Marshall Islands.

Marisa Caputo, special assistant to the Office of Human Radiation Experiments at the Department of Energy noted *"Vulnerable populations were subjects in some cases because they were 'needy'. Such patients often were grateful for better care, food, etc., as perceived by the researcher, in exchange for participation in the experiments and may have thought they 'owed' medical establishments for free or low-cost treatment."*

3 ADDITIONAL PROJECTS

The Advisory Committee was directed to

1. study how each agency that currently conducts or funds research involving human subjects regulates and oversees this activity;
2. review documents and consent forms of research projects that are today sponsored by the government to develop insight on protecting the rights and interests of the subjects; and
3. interview 1,900 patients receiving outpatient medical care in private hospitals and federal facilities throughout the country to ascertain whether they were currently, or had been subjects of research, and why they had agreed or refused to participate.

4. develop clarification of the meaning of minimal risk in nontherapeutic research on children;
5. develop regulations to cover the conduct of research with institutionalized children; and
6. develop guidelines for research on adults of questionable competence, particularly in more-than-minimal risk offers no direct medical benefit.

THE MANHATTAN PROJECT

1940s — Plutonium-injections were performed on 18 terminally ill patients in secret to trace it through the body in efforts to develop data needed to protect the health and safety of nuclear weapons workers. The subjects of the study, many of whom developed cancers, were followed throughout the remainder of their lives by medical researchers in the 1990s — *families learned, through media reports, that plutonium had been used.*

The subjects were given 4.6-6.5 micrograms of plutonium that was thought to be 5½ times the body's burden deemed acceptable over a 50-year period. All the subjects suffered from cancer, Addison's disease, heart disease, cirrhosis and/or other pathological conditions. New, stricter standards for exposure to plutonium for workers and nonworkers were published in 1950.

PREGNANT WOMEN

1940s — Vanderbilt University conducted an experiment on 800 pregnant women who were fed radioactive iron to establish nutritional guidelines during pregnancy. *No information regarding the risks to mother or fetus was provided.*

EXPERIMENTS WITH PRISONERS

64 healthy prisoners received irradiation to the testes for the purpose of learning the effects of external irradiation (up to 600 rads), such as might be experienced by astronauts in space. They were a literally captive population who bore risks to which no other group of experimental subjects had been exposed to then or now.

These experiments took place at Washington State Prison by the Washington State University and a similar study was conducted among prison inmates in Oregon.

Inmates signed consents that warned of the risk of sterility and radiation burns, but not of testicular cancer. The inmates received \$200.

CHILDREN

Research sponsored by the AEC and Quaker Oats involved feeding cereal containing radioactive iron and calcium to the residents of the Fernald School for retarded boys from 1946 to 1956. The study was performed in an attempt to determine whether cereal would block the absorption of the isotopes. *Radioactivity was not mentioned to the parents.*

13 INTENTIONAL RELEASES

The releases were to test intelligence equipment, the potential of radiological warfare and the mechanism of the atomic bomb. While the risk was relatively small, the releases often took place in secret and remained secret for years. Human subjects were not the priority of studies.

NUCLEAR WEAPONS DEVELOPMENT

Workers who mined uranium for the AEC in the western United States from 1940-60s and residents of the Marshall Islands whose Pacific homeland was irradiated as a consequence of a hydrogen bomb test in 1954 were two populations were at risk who consequently became subjects of observational research.

APOLOGIES AND COMPENSATION

The government should deliver a personal, individualized apology and provide financial compensation to the subjects or their next of kin in which:

- secrecy efforts denied individuals the opportunity to pursue potential grievances; or
- there was no prospects of direct medical benefit; or
- controversial interventions were presented as standard practice and physical injury resulted.

NATIONAL SECURITY AND PUBLIC TRUST

The Advisory Committee recommended adoption of federal policies requiring:

1. Informed consent of all human subjects of classified research which is not subject to exemption or waiver and
2. That classified research is permitted only after review and approval of an independent panel of appropriate non-governmental experts and citizen representatives.
3. There must be independent review of environmental releases to assure that the action is needed, that risk is minimized and that records will be kept to assure proper accounting to the public at the earliest date consistent with legitimate national security concerns.
4. An appropriate government agency, such as the Environmental Protection Agency, should provide and maintain direction with cleared personnel.
5. Significant advances in the system for the protection of rights of human subjects.
6. Minimize the potential for unrealistic expectations among patients with serious illnesses about the prospects of direct medical benefit with participation.
7. Conduct open and public forums on ethics rules for human subject research.

CURRENT REGULATIONS ON SECRECY

Human research can *still* be conducted in *secrecy today* and *informed consent* can be *waived* under some conditions. Intentional releases could take place in *secret* today under current environmental laws.

CONTEMPORARY RESEARCH

The Advisory Committee found:

- human research involving radioisotopes is currently subjected to *more safeguards* and levels of review than most other areas of research on human subjects;
- about 40-50% of human subjects research poses no more than minimal risk of harm to subjects;
- found examples of complicated, higher risk studies which included excellent consent forms;
- there was little evidence that patient-subjects felt coerced or pressured to participate; and
- found evidence suggesting serious deficiencies in some parts of the system to protect the rights and interests of subjects.

KEY FINDINGS

In the great majority of the cases, the experiments were conducted to advance biomedical science;

some were conducted to advance national interests in defense or space exploration; and some served both purposes.

The majority of human radiation experiments identified by the Advisory Committee involved radioactive tracers administered in amounts that are likely to be similar to those used in research today. *Most of the studies involved adult subjects and are unlikely to have caused physical harm.*

In some nontherapeutic tracer studies involving children, radioisotope exposures were associated with increases in the potential lifetime risk of developing thyroid cancer that would be considered unacceptable today.

Several studies were identified in which patients died soon after receiving external radiation or radioisotope doses in the therapeutic range that were associated with acute radiation effects.

That research should proceed only with the consent of the human subject was recognized at an early date by the AEC, the Defense Department and the National Institutes of Health. *However, there is little evidence of rules or practices of consent except in research with healthy subjects.*

There was little attention paid during this period to issues of fairness in the selection of subjects.

Government officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive direct medical benefit.

To the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices in place.

During the 1944-1974 period, the government conducted several hundred intentional releases of radiation into the environment for research purposes. In only a *very few* of these cases was radiation released for the purpose of studying its effects on humans.

For both the Green Run at Hanford and the RaLa tests at Los Alamos, where dose reconstructions have been undertaken, it is unlikely that members of the public were directly harmed solely as a consequence of these tests. These releases were conducted in secret, but some information was made public during the life of the Advisory Committee.

CONCLUSIONS

Research can bear incalculable value in promoting and protecting national security and the advancement of science and medicine. The Cold War radiation experiments have been credited in helping to establish the nuclear medicine profession. Scientific and medically valuable information had been gained.

The sensationalism of the media can have a negative effect on the patient population undergoing nuclear medicine testing because patients may delay or avoid tests and/or treatments involving radiation.

Some individuals are put at risk for the benefit of the greater good.

Actions in the future must proceed through means that safeguard the dignity, health and safety of the individuals/groups who may be put at risk in the process.

*The Advisory Committee recommendations included changes in:
Institutional Review Boards;*

Interpretation of ethics rules and policies;

Conduct of research involving military personnel as subjects;

Compensation for research injuries;

Accountability and sanctions for ethics violations;

Development of a more common understanding among the public of research purposes and limitations; and

Openness in government and in biomedical research.

PUBLIC INFORMATION

The complete records assembled by the Advisory Committee are available to the public through the National Archives. The final report contains "A Citizen's Guide to the Nation's Archives: Where the Records are and How to Find Them" which explains how to locate personal medical records and how to use the Advisory Committee's volumes.

CONCLUSIONS

"Let the lessons of history remind us all that the best safeguard for the future is an informed and active citizenry."

This concludes the Unit 16. Please proceed to the unit questions and complete the required personal data.

Some Important Terms and/or Concepts in Unit 16

The AEC research was part of a larger postwar transformation of biomedical research through the infusion of substantial government monies and technical support.

Autonomy is defined as the right of every individual to determine his or her own destiny.

Three types of consent exist.

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Institutional Review Boards (IRBs) must approve all federally-funded proposed research on human subjects.

The Patient Self-Determination Act mandates that healthcare institutions receiving Medicare and Medicaid funding provide written information about patient's rights to participate in medical decision making and the formulation of advance directives.

From April 1994-July 1995, the Advisory Committee on Human Radiation Experiments investigated reports about possible unethical experiments involving human subjects and radiation funded by the government from 1944 through 1974.

"People would get sick if they knew what went on," says Fred Boyce (at the Fernald School, with other members of the "Science Club").

Revolt of the Innocents

An angry victim seeks justice for schoolmates once treated as guinea pigs

Fred Boyce, a Norwell, Mass., real estate broker and carnival concessionaire, was pulling into a parking lot in early 1994 when he was jolted by news on the car radio. A federal investigation had concluded that in the 1940s and '50s, scientists from the Massachusetts Institute of Technology had con-

Photographs by Ed Quinn/SABA

ducted radiation experiments on unwitting children at the Walter E. Fernald State School in Waltham, Mass. "What! That can't be right," thought Boyce, 57. "That's us! That's me!"

In all, at least 74 boys had been fed oatmeal laced with radioactive isotopes that acted as tracers while the food was digested. The experiments,

sponsored by the Quaker Oats Co.—and approved by the federal Atomic Energy Commission—were undertaken in part to match advertising claims by rival Cream of Wheat that nutrients in the latter cereal traveled throughout the body. The studies were among dozens of government-sanctioned radiation experiments,

PEOPLE 5/18/98 113

classified Top Secret, that were conducted during the Cold War on children, pregnant women, hospital patients and prisoners.

Boyce, recalling how he had been lured into the experiments five decades ago with gifts of Hopalong Cassidy mugs, boat rides and outings to Boston Braves baseball games, was tempted at first to let bygones be bygones. He had spent a lifetime trying to forget his years at the brick-walled institution on the outskirts of Boston. But the more he thought about it, the more determined he became to seek compensation for himself and his fellow guinea pigs—who had been told they were the lucky members of the school's "Science Club." "I said to myself, 'Go and open this thing up. What are they going to do to me?'" says Boyce. He began tracking down his schoolmates, many of whom were reluctant to join the suit, fearful of being stigmatized.

Thanks in part to Boyce's efforts, he and about 40 other victims accepted \$1.85 million on April 6 from MIT and Quaker Oats to settle a class-

action suit against the university and the food company. Now, says Boyce, they will press forward with suits against the federal government, for providing the radioactive material, and against the state, for allowing the experiments. "The state guys were rats," he says. "They were supposed to act as our parents."

When the MIT scientists first stepped into Fernald's grim wards, they had little trouble enticing Boyce to participate, along with dozens of other Fernald boys who had been orphaned or taken from dysfunctional families, labeled—often inaccurately—feeble-minded and warehoused among hundreds of severely retarded adults and children. Daily life was a numbing mix of boredom and brutality. Boyce recalls how an attendant watching over a ward of 36 children would force them to sit on wooden benches for hours with arms folded. "If you unfolded your arms," he says, "you were whacked." Any opportunity to escape Fernald was so

irresistible, Boyce says, that had the scientists offered an outing in exchange for taking arsenic, he would have agreed: "My hand is up! I want it! We're going to a ball game!"

The young Boyce was certain that the scientists would be his salvation. They would witness the beatings, humiliations and daily deprivations and put a stop to them. "I was sure they were going to say, 'What the hell is going on here?'" he recalls.

But if the researchers became aware of conditions, they never let on. Rather, they forged ahead with their experiments without ever mentioning radiation. Indeed, MIT scientist Robert Harris noted that recalcitrant children might be "induced to change their minds [by emphasizing] the Fernald Science Club angle."

The experiments remained secret until 1993, when Secretary of Energy Hazel O'Leary, breaking precedent, began declassifying documents and

I 'The state guys were rats. They were supposed to act as our parents'

urging compensation. The following year a state panel confirmed that small amounts of radioactive calcium and iron were fed to at least 74 Fernald residents, leading MIT President Charles Vest and President Clinton to apologize for the tests conducted without informed consent. Nonetheless, a presidential advisory committee maintains that the experiments' participants are not entitled to federal compensation because the trace doses of radiation they received had no effect on their health.

To Science Club alum Joe Almeida, 55, such claims are infuriating, particularly because a significant amount of radioactive isotopes supplied for the experiments remains unaccounted for. "You've got to think about it all the time. It's bad enough that [the state] took our childhood away," says Almeida, now a bus dri-

ver at Fernald, but in ongoing negotiations state officials "have the attitude, 'Give them a few cents and shut them up.'" Michael Mattchen, a lawyer representing Boyce and the others, says that his clients' rights were violated and that they are now

suffering from emotional distress. "The fact that they weren't maimed or killed is a pretty lame defense."

Boyce was sent to Fernald in 1949, at age 8. The second of 13 children taken from his mother when she could no longer care for them after her husband died in 1941, he had been living in a foster home—his fifth—when his foster mother, too, passed away. He and four foster siblings were labeled mentally retarded and taken to Fernald. Increasingly rebellious as he grew

into his teens, Boyce was occasionally confined in a high-security unit at the institution. Finally, in 1959, Fernald's administrators discharged him, then 18 and virtually unable to read or write.

After earning \$1 an hour hammering ladders together for the now-defunct Grifford Ladder Company in Waltham, Boyce later began traveling the country as a carnival worker, eventually running his own concessions. Briefly married and divorced in 1987, he lives in a fashionable Boston suburb and travels the carnival circuit eight months a year. Self-educated, he devotes much of the rest of his time to helping less-fortunate Fernald alumni prepare for future suits. "Fred's not just for Fred," says Joe Almeida. "Fred is for everybody."

- Bruce Frankel
- Eric Francis in Norwell

‘The fact that they weren't maimed or killed is a pretty lame defense’

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USA
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FRIDAY, JANUARY 23, 1998

U.S. to fund victims' radiation checks

By Steve Sternberg
USA TODAY

Federal energy officials agreed Thursday to pay \$5 million to start a medical screening program for 14,000 civilians exposed to Cold War radiation released from the Hanford Nuclear Reservation, near Richland, Wash.

The decision breaks a stalemate between the U.S. Department of Energy (DOE) and the federal Agency for Toxic Sub-

stances and Disease Registry (ATSDR), which was seeking \$12.9 million from the DOE to monitor the health of these potential radiation victims.

More broadly, the announcement marks the first time that the DOE, the agency in charge of the nation's nuclear arsenal, has acknowledged an obligation to pay for medical screening needed by people exposed to radiation leaks.

Energy undersecretary Ernest Moniz made the surprise

announcement in Richland. "We support these important health studies and will work with ATSDR and Congress to assure continued funding."

Yet the award falls short of the \$12.9 million ATSDR wanted for medical monitoring, a registry of radiation victims and cooperative environmental health programs with nine native American tribes.

The DOE was obligated to pay under the 1986 amended Superfund law but protested

that the money was needed for environmental cleanup.

Staffers on the House Commerce Subcommittee on Government Oversight and the Senate Governmental Affairs Committee this week began investigating the funding dispute.

USA TODAY reported last week that thousands of Hanford-area residents were exposed to the equivalent of 25 mammograms from 1944 to 1961, raising the risk of thyroid cancer by 20%-50%.

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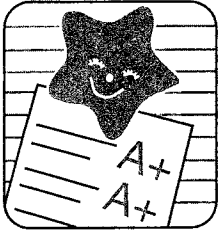
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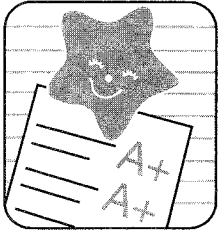
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A handwritten signature in black ink, appearing to read 'Carolyn', is written over a horizontal line.

**Carolyn J. Frigmanski, M.A., B.S.R.T. ®
Founder, S.T.A.R.S.**

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Unit Number 13

Title: Virtual Reality in Medical Applications

1. A term(s) used to describe three dimensional, computer generated environments that simulate reality is
 - a. virtual spacing
 - b. artificial cybernetics
 - c. artificial intelligence
 - d. cyberspace
2. Virtual reality applications evolved over time based on the concurrent development of
 - a. magnetic resonance
 - b. NASA flights
 - c. genetic engineering
 - d. LCD displays and VPL Dataglove
3. The degree to which a subject feels that they are actually present in a virtual environment is
 - a. kinesthetic feedback
 - b. immersion
 - c. interactivity
 - d. kinetic feedback
4. Robotic systems have been designed to use miniature linear accelerators in the practice of
 - a. endoscopy
 - b. bronchoscopy
 - c. neurosurgery
 - d. orthopedics
5. Success in virtual reality applications relies on the interfacing of
 - a. x ray images
 - b. hospital computer systems
 - c. computer downtime
 - d. robotic devices
6. Some of the advantages of using virtual reality in anesthesia include, but are not limited to
 - a. allowing errors to be made & consequences explored with potential lawsuits
 - b. allowing control of multiple variables in a situation
 - c. keeping surgeons in the operating room at all times
 - d. simulating actual events without risk to patient
7. The first practical applications of virtual reality in laparoscopic surgery involved the
 - a. gall bladder and liver
 - b. small bowel and colon
 - c. ovaries and uterus
 - d. appendix
8. Applications in interventional radiology include, but are not limited to
 - a. ultrasound biopsy
 - b. stereotactic breast biopsy
 - c. pacemaker lead introduction
 - d. thrombosis practice
9. Surgical suites of the future which will permit virtual reality "operations" will have
 - a. simplistic visual equipment
 - b. single phase x-ray equipment
 - c. traditionally taught surgeons
 - d. dedicated staff and virtual reality surgeons
10. Virtual reality can be used in other medical applications such as
 - a. employee scheduling
 - b. biomedical engineering
 - c. strategic budget planning
 - d. DNA and biomolecule manipulation

11. Nursing education can be changed dramatically with virtual reality applications based on the fact that
- a. nurses do not have to practice empathy
 - b. practice care plans can be eliminated
 - c. accreditation processes can be minimized
 - d. nursing units can build and control traffic patterns

12. — 16. Match the future specialist in medical applications of virtual reality below

- | | |
|----------------------------------|--|
| _____ bioengineer | a. delegates patients to appropriate specialist on team |
| _____ endoscopist | b. performs exams on gall bladder, liver, appendix, etc |
| _____ physician director | c. decides financial and political aspects of procedure |
| _____ health economist | d. consulted about appropriate instrumentation |
| _____ interventional radiologist | e. treats organs available to skill level with assistance by x-ray imaging |

17. At the conclusion of the 20th century, virtual reality in medicine has been hampered by
- a. fast computers
 - b. fear by prospective patients
 - c. lack of support by doctors
 - d. cumbersome equipment

18. The continued application of virtual reality in medicine will rely on
- a. government funding
 - b. insurance reimbursement
 - c. patient input
 - d. supportive popular attitudes and demand

19. True or false Virtual reality will be the anticipated imaging and medical procedure of the next millennium.

20. True or false The applications of virtual reality in medicine is no longer science fiction.

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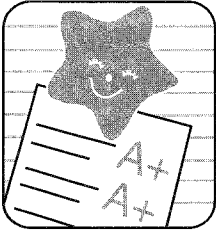
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Unit Number: 14

Title: PICA: A Look at PICA Versus Foreign Bodies

1. The term "PICA" literally means
 - a. place in cavities
 - b. "dirt eater"
 - c. magpie
 - d. crow
2. Patients with PICA conditions may consume:
 - a. poisonous substances
 - b. overdoses of medications
 - c. high carbohydrates
 - d. feces, paint, and/or string
3. The phenomenon of geophagy has been known to occur on every continent and involves
 - a. difficulty swallowing
 - b. raw meat eating
 - c. eating vegetarian meals only
 - d. eating all non-edible food items
4. Geophagy, a form of PICA, was observed and documented in:
 - a. some prehistoric cavemen
 - b. some Native American groups
 - c. European explorers
 - d. U.S. slaves
5. PICA occurs most often in populations who have
 - a. low socioeconomic status
 - b. high socioeconomic status
 - c. middle socioeconomic status
 - d. all socioeconomic categories
6. PICA may be manifested most often in children whose family environment includes
 - a. overprotection by parents
 - b. no biological parenting i.e. orphans
 - c. physically and verbally abusive relatives
 - d. lack of mothering and available food
7. Emotional factor(s) may influence the development of PICA such as
 - a. adequate nurturing by the mother
 - b. older siblings
 - c. adequate nurturing by the father
 - d. separation from one or both parents
8. PICA in children may have some biological foundation such as
 - a. renal failure
 - b. SIDS
 - c. organic brain damage
 - d. cancer
9. PICA occurs most frequently in children
 - a. during the first 2 years of life
 - b. between the ages of 1-6
 - c. during puberty
 - d. during late teen years
10. Increasing frequency of PICA has been demonstrated in
 - a. families with European heritage
 - b. grandmothers of children with PICA
 - c. all siblings in the same family
 - d. children who had PICA in their early years



Unit 15

Title: Evolutionary Process of Disease

1. Changing disease patterns have been affected historically by:
 - a. epidemics
 - b. genetic improvements in man
 - c. occupational injuries
 - d. social structure and economic exploitation

2. The long-term survival of an infectious agent is dependent on:
 - a. its ability to multiply
 - b. its length of life
 - c. its host needs
 - d. its response to antibiotics

3. Our bodies have several lines of defense for protection from disease that include
 - a. a continuous genetic link
 - b. our neurological responses
 - c. mutational changes over time
 - d. our sense of pain, touch, smell, taste, hearing

- 4-8. Match the causal agent with its appropriate definition below:

<p>___ a. nutritional</p> <p>___ b. genetic</p> <p>___ c. physiological</p> <p>___ d. chemical</p> <p>___ e. biological</p>	<p>1. Alterations in our chromosomal configuration.</p> <p>2. Temporary events/changes occurring in our normal life span.</p> <p>3. Invading living organisms, i.e. parasites/viruses, etc.</p> <p>4. Gases and toxic materials that pollute our environment.</p> <p>5. Lack or overabundance of specific food substances.</p>
---	--

9. The first population of human beings who existed on earth 5 million-12,000 years ago who were studied in an anthropologic manner were:

<p>a. ape-like foragers</p> <p>b. hunter/gatherers</p>	<p>c. pre-industrial societies</p> <p>d. village food producers</p>
--	---

10. The name used to describe a classification of diseases involving exposure to animal pathogens is:

<p>a. latent viral</p> <p>b. primate</p>	<p>c. zoonoses</p> <p>d. plagues</p>
--	--------------------------------------

11. The population of people called Village Food Producers experienced disease patterns influenced by:
 - a. good sanitation/waste disposal
 - b. failure to trade between villages/regions
 - c. domesticating animals from the wilderness
 - d. increased number of bowel to mouth disease

12. The pre-industrial city populations experienced disease patterns influenced by:
- a. major epidemics and world exploration
 - b. development of antibiotics
 - c. rise of labor movement
 - d. development of pastuerization
13. Major scientific and medical discoveries, such as the discovery of x-rays, occurred in the lifetimes of which population?
- a. Techno-Industrial/modern
 - b. Village Food Producers
 - c. Agri-Industrial
 - d. Hunter/gatherers
14. The term used to described diseases resulting from treatment or during hospitalization is:
- a. zoonoses
 - b. iathogenic
 - c. latent viral
 - d. self generated
15. The predominance of particular disease entities can and are influenced by these factors:
- a. social environment and modernization
 - b. race, gender and social class
 - c. work, die and exercise
 - d. all of the above
- 16-20. Match the lifestyle characteristics with the populations:
- | | |
|---|------------------------|
| ___ little tobacco and alcohol use | A. paleolithic |
| ___ increased sugar and calorie intake | |
| ___ increased cancer and diabetes | B. contemporary/modern |
| ___ increase infant mortality and infectious diseases | |
| ___ decreased exercise and stamina | |

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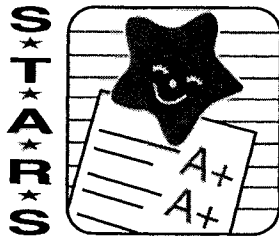
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Unit Number 16

Title: Ethics of Human Radiation Experiments

1. The primary purpose of the Manhattan Project was to:
 - a. expose large populations to radiation in New York
 - b. develop the atomic bomb to speed up an end to World War II
 - c. investigate building a nuclear power plant in Manhattan
 - d. continue Einstein's research on atomic energy and the theory of relativity
2. The primary purpose of the AEC was to:
 - a. develop radioisotopes for medical research
 - b. work on hydrogen bomb plans
 - c. study Atomic Bomb survivors
 - d. develop dose limits for radiation workers
3. The Ethics principle that describes the individual's right to determine his or her destiny is
 - a. consent
 - b. beneficence
 - c. autonomy
 - d. eminence
4. Seeking a signed consent from a patient is an example of
 - a. implied consent
 - b. simple consent
 - c. no special type of consent
 - d. express consent
5. The legal capacity to give consent can be given by
 - a. a child
 - b. a teenager
 - c. an incompetent adult
 - d. individual obligated by court order
6. Touching a patient without his/her consent can result in
 - a. assault
 - b. battery
 - c. negligence
 - d. autonomy
7. Guidelines for ethical behavior, informed consent and other aspects for human experimentation developed after World War II was known as
 - a. Schloedorff case
 - b. Canterbury versus Spence
 - c. Nuremberg Code
 - d. PSDA
8. In 1974, the National Research Act developed "groups" to approve all federally funded propose research on human subjects called
 - a. Institutional Review Boards
 - b. Clinton Committee
 - c. Cardoza committees
 - d. Manhattan project
9. From 1944-1974 the number of human radiation experiments funded by the United States government was
 - a. 1,000
 - b. 500
 - c. 4,000
 - d. 10,000
10. One of the biggest problems the United States government faces relative to these historical human experiments and the general public is
 - a. open policy of disclosure
 - b. legacy of distrust
 - c. political support in the future
 - d. lack of financial support

11. — 14. Identify these populations with the intended purpose of the experiment below

- | | |
|--|---|
| _____ pregnant women | a. evaluate external radiation effects for NASA astronauts |
| _____ mentally delayed children | b. radioactive iron and calcium in cereal |
| _____ prisoners | c. plutonium injections to develop health and safety of nuclear weapons workers |
| _____ terminally ill patients in 1940s | d. radioactive iron to establish nutritional guidelines |

15. Recommended improvements in the area of ethics since the disclosure of the historical human radiation experiments include

- no advances in protecting patient rights
- elimination of open, public forums on ethics rules
- non-publicity of unethical experiments in the United States
- reduction of unrealistic expectations among patients with serious illnesses about prospects of direct medical benefit

16. The purpose in conducting the majority of human radiation experiments was to

- | | |
|-----------------------------|---|
| a. advance general science | c. create better genetically developed human beings |
| b. create a uniform society | d. advance national interests in space exploration |
17. Selection of subjects in the experiments from 1944-1974 was
- | | |
|-------------------------------------|--|
| a. unfair to race and social status | c. only directed to women and children |
| b. fair to race and social status | d. reserved for senior citizens |

18. The Advisory Committee recommended adopting federal policies involving intentional environmental releases that would

- | | |
|---|--|
| a. prevent disclosure to the general public | c. require congressional approval |
| b. minimize risk and be directed by the EPA | d. minimize federal government control |
19. The Advisory Committee recommended the rules and practices for informed consent be provided to
- | | |
|---|--------------------------|
| a. women and children | c. all research subjects |
| b. mentally challenged and/or physically disabled | d. all senior citizens |

20. The Advisory Committee recommendations for future human radiation research included

- | | |
|--|--|
| a. no compensation for research injuries | c. secrecy to prevent discontinuation of experiments |
| b. changing the principles of ethics | d. openness in government and biomedical research |

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